HERMES DECLARATION
EXHIBIT 4

US005314446A

United States Patent [19]

Hunter et al.

[11] **Patent Number: 5,314,446**

[45] **Date of Patent: May 24, 1994**

[54] **STERILIZED HETEROGENEOUS BRAIDS**

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[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

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3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
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4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
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4,946,467	8/1990	Ohi et al.	606/228
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Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

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FIG-1

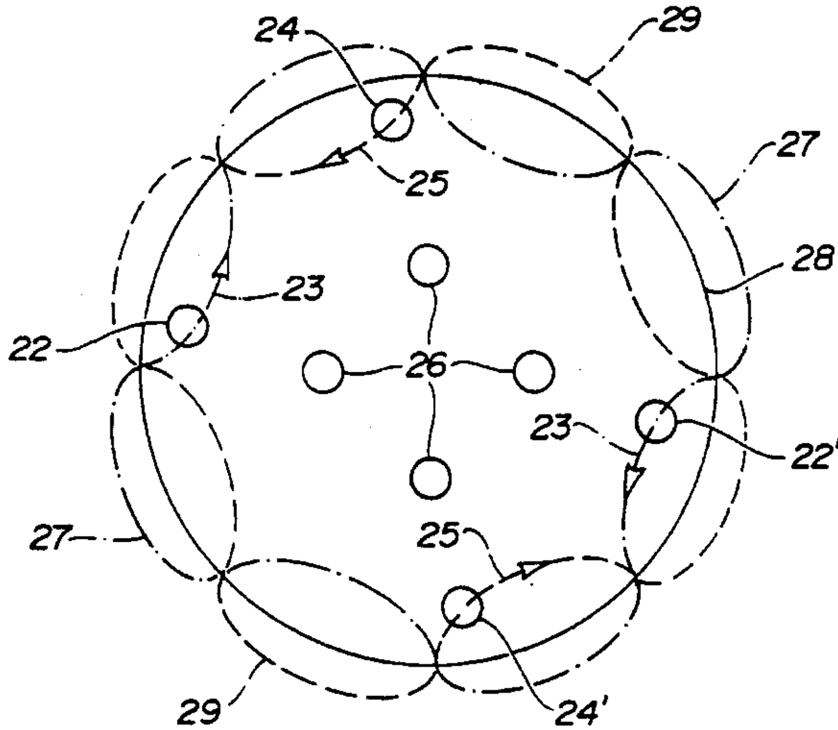


FIG-2

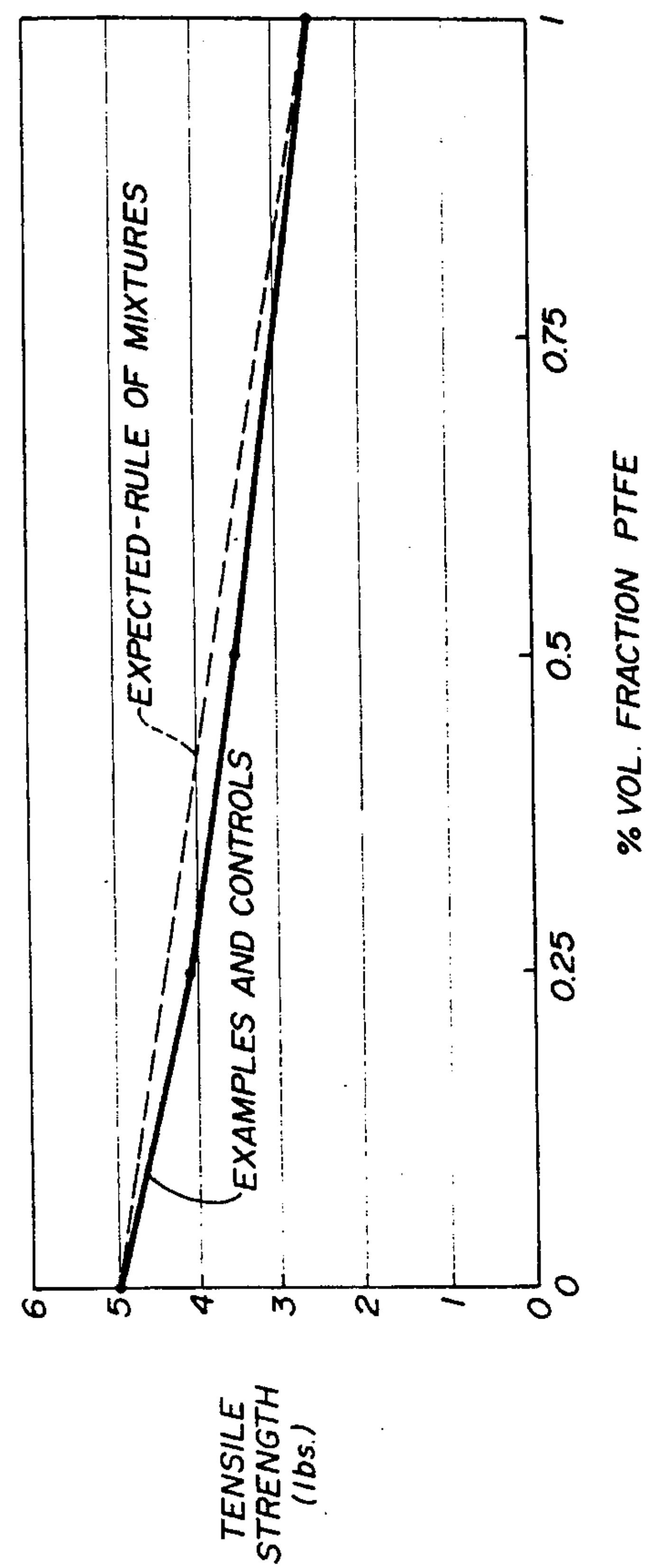
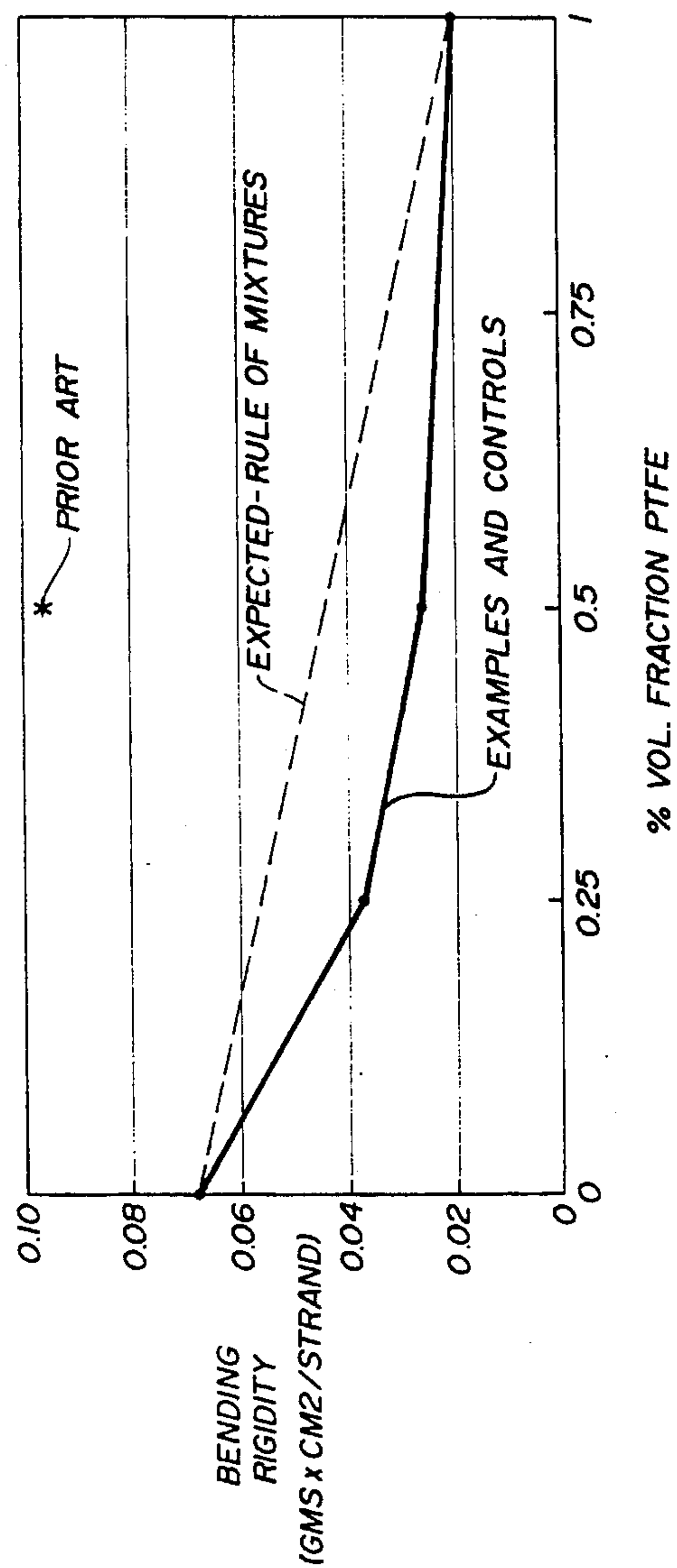

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE
BENDING RIGIDITY (GMS x CM2/STRAND)

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers **22**, **22'** and

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24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)\,(P_a)+(Vf_b)\,(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

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HERMES DECLARATION
EXHIBIT 5

United States Patent [19]

Silvestrini et al.

[11] **Patent Number: 4,610,688**

[45] **Date of Patent: Sep. 9, 1986**

[54] **TRIAXIALLY-BRAIDED FABRIC PROSTHESIS**

[75] Inventors: **Thomas A. Silvestrini**, East Lyme; **Joseph E. Laptewicz, Jr.**, Groton, both of Conn.

[73] Assignee: **Pfizer Hospital Products Group, Inc.**, New York, N.Y.

[21] Appl. No.: **481,612**

[22] Filed: **Apr. 4, 1983**

[51] **Int. Cl.**[4] **A61F 2/06**; A61F 2/24

[52] **U.S. Cl.** .... **623/1**; 623/2; 623/12; 128/92 C

[58] **Field of Search** .... 3/1, 1.4, 1.5; 128/92 C, 335

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Primary Examiner—Richard J. Apley
Assistant Examiner—David J. Isabella
Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Lawrence C. Akers

[57] **ABSTRACT**

A novel prosthesis for use in repairing or replacing soft tissue is disclosed, which comprises a triaxially-braided fabric element having interwoven first, second and third sets of fibers, with the fibers of the second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of the first set. An elongated ligament prosthesis exhibiting the desired properties of high strength and high elasticity may be prepared by selecting high elasticity fibers for the first set, orienting said first set of fibers in the longitudinal direction of the prosthesis and selecting fibers having high yield strength and high Young's modulus for the second and third sets. A tubular prosthesis in which high elasticity fibers are oriented in the longitudinal direction is highly suitable for use as a vascular prosthesis. A prosthesis of the invention may also be manufactured in the form of a prosthetic heart valve leaflet.

14 Claims, 6 Drawing Figures

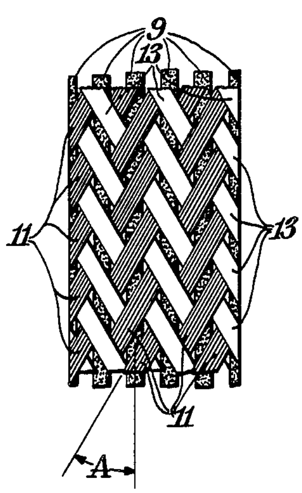


Fig. 1.

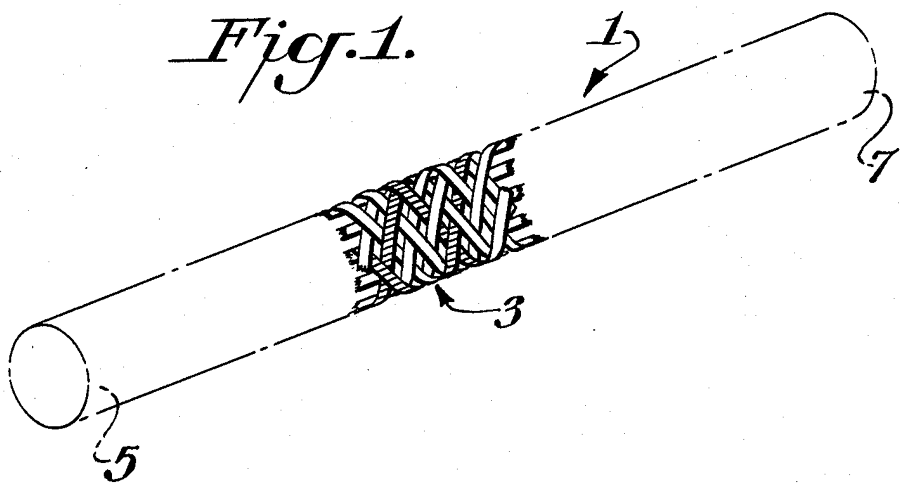
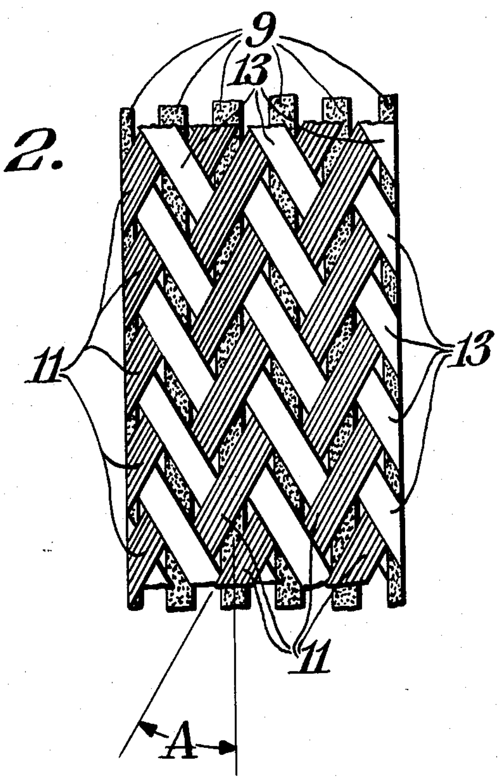
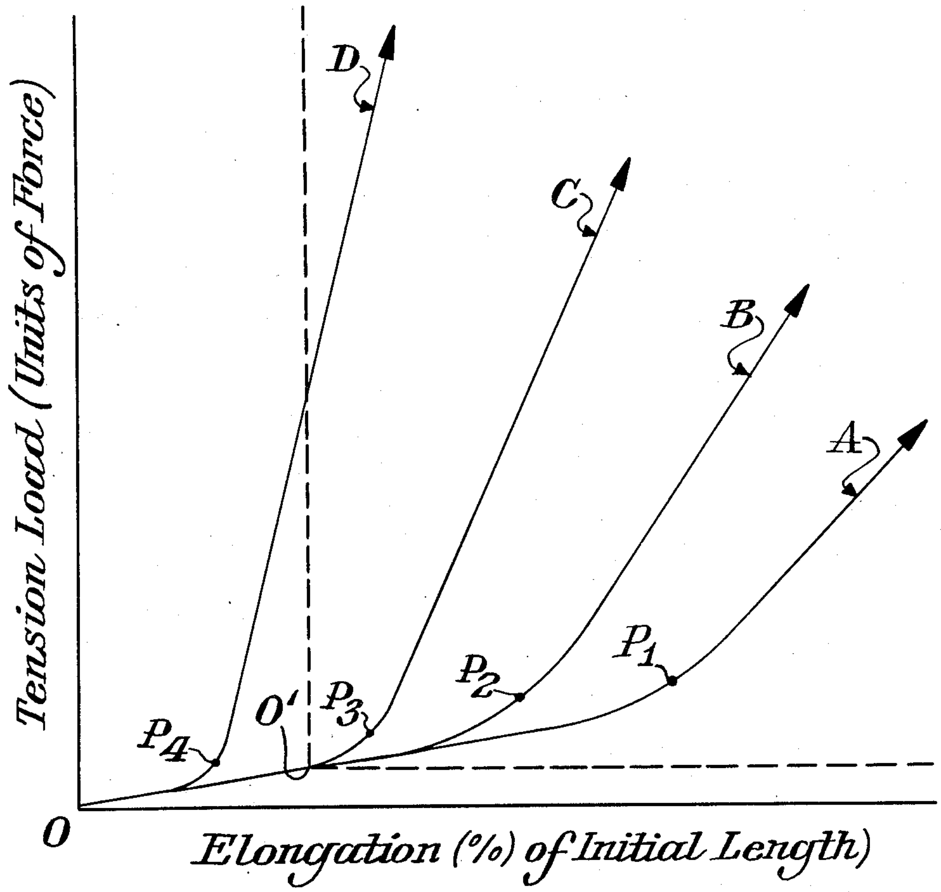


Fig. 2.





Tension Load (Units of Force)
Elongation (%) of Initial Length)
O
O'
D
C
B
A
P1
P2
P3
P4

Fig.3.

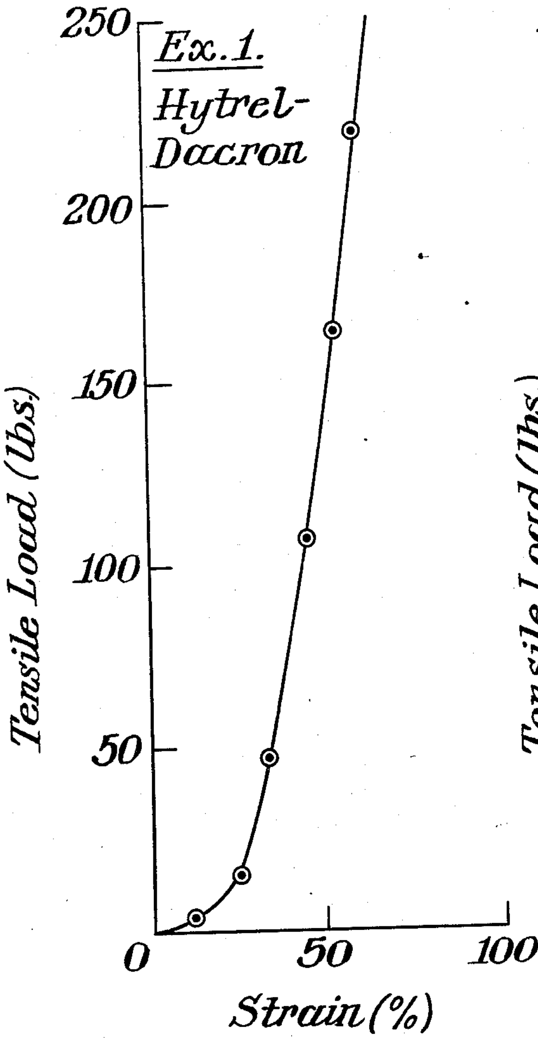

Ex. 1.
Hytrel-Dacron
Tensile Load (lbs.)
250
200
150
100
50
0
50
100
Strain (%)

Fig. 4.

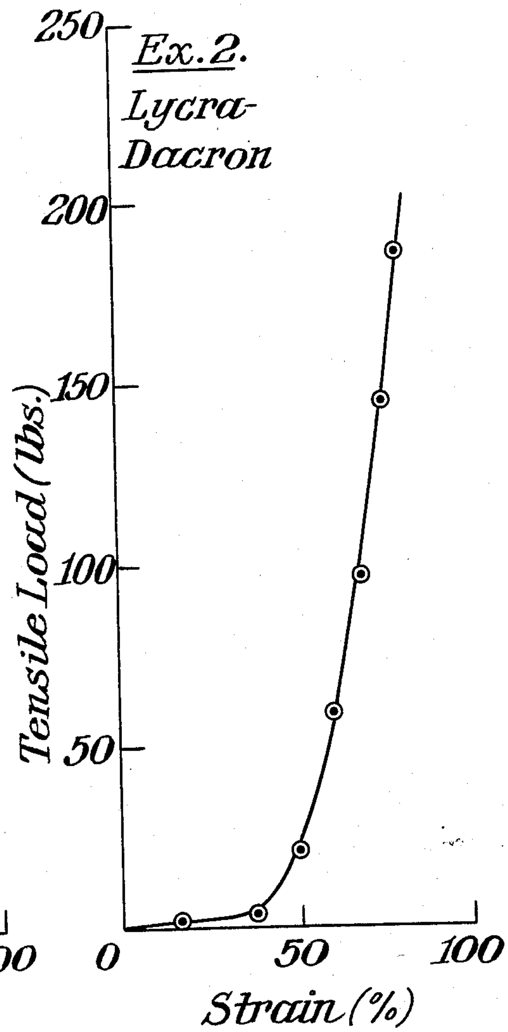

Ex. 2.
Lycra-Dacron
Tensile Load (lbs.)
250
200
150
100
50
0
50
100
Strain (%)

Fig. 5.

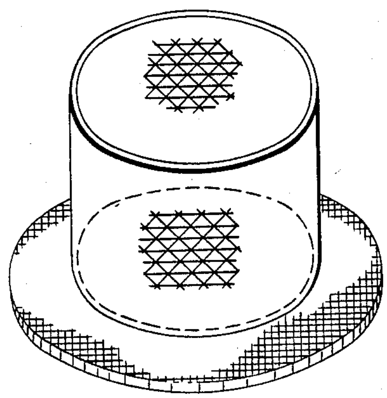


Fig. 6.

TRIAXIALLY-BRAIDED FABRIC PROSTHESIS

BACKGROUND OF THE INVENTION

The natural ligaments are elongated bundles of collagenous soft tissue that serve, among other things, to hold the component bones of joints together. The surgical treatment of diseased or damaged ligaments, e.g. the anterior cruciate ligament, has been severely hampered by the unavailability of a suitable, generally accepted ligament prosthesis. The desired characteristics for a ligament prosthesis include appropriate size and shape, biological compatibility, capability of being readily attached by the surgeon to the body of the patient, high fatigue resistance and mechanical behavior approximating that of the ligamentous tissue sought to be repaired or replaced.

The latter desired characteristic is particularly important. Natural ligaments are both strong and highly elastic, which qualities are generally not found together in a single material. Thus, for example, the anterior cruciate ligament of normal adult humans exhibits a yield point in tension of about 50 kg. at a reversible elongation of about 28%, and a break point of about 60 kg. (Typical adult human tendons are stronger and less elastic.) A number of ligament and/or tendon prostheses are known in which the load bearing body portion is fabricated essentially of a single synthetic material (see, e.g., U.S. Pat. Nos. 3,176,316; 3,613,120; 4,127,902; 4,149,277; 4,209,859; 4,255,820; 4,329,743 and 4,345,339; U.K. Pat. No. 1,602,834 and European Published Patent Appln. 51,954). These monocomponent devices generally possess insufficient longitudinal elasticity and some also exhibit inadequate longitudinal break strength. As a result of their insufficient elasticity, this type of prosthesis must be forced into the region of plastic deformation to achieve the longitudinal elongation desired for normal anatomical function, e.g. flexion of a joint, which of course permanently impairs the mechanical function of the prosthesis.

Recently, ligament prostheses have been disclosed in U.S. Pat. Nos. 4,246,660 and 4,301,551 in which the load bearing body portion is a bicomponent structure comprised of one material that imparts strength to the prosthesis and another material that imparts elasticity. The use of these prostheses alleviates the disadvantages described above for the monocomponent type of prosthesis. However, the prostheses disclosed in the '660 and '551 Patents are complex in construction and their methods of attachment to the body of the patient involve rather complicated surgical procedures.

A recent thesis (Elizabeth E. Fitzgerald, "Mechanical Behavior of Bicomponent Braids as Potential Surgical Implants", Master of Science Thesis, Cornell University, August 1979) has disclosed the use of a braided bicomponent tube as a ligament prosthesis. In this prosthesis two interwoven sets of polymeric fibers, one of a strong material and the other of an elastic material, are helically-disposed in the wall of the tube and oriented at a fixed angle with respect to one another. Each set of fibers is oriented at the same acute angle with respect to the longitudinal direction of the tube. The prosthesis may additionally comprise a monocomponent polymeric filament core.

The prosthesis disclosed in the Fitzgerald thesis has certain inherent disadvantages. First, since the fibers in the two helically-disposed interwoven sets are not idential, the prosthesis is not balanced and will tend to twist

during longitudinal elongation. Second, since the set of helically-disposed elastic fibers is angulated with respect to the longitudinal direction of the prosthesis, only a minor amount of the work performed in elongating the prosthesis longitudinally is converted to elastic energy stored in the extended set of elastic fibers. Undesirably large portions of said work are converted to elastic energy stored in the other set of strong fibers or dissipated as friction in the extending trellis-like bicomponent braided structure.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a ligament prosthesis of simple construction that exhibits a yield strength in tension and a longitudinal elasticity that are at least comparable to that of a human ligament and a resistance to longitudinal elastic deformation in tension that approximates that of a human ligament.

Is is another object of the invention to provide a balanced braided prosthesis of such construction that its longitudinal load-strain behavior can be readily "fine-tuned", while maintaining balance, to suit particular applications by changing component materials and/or braiding variables.

These and other objects of the invention are achieved with a novel prosthesis for use in repairing or replacing soft tissue comprising a triaxially-braided fabric element containing interwoven first, second and third sets of fibers, with the fibers of said first set being oriented in substantially the same direction, the fibers of said second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of the first set, and the fibers of one of said three sets having greater elasticity than the fibers of one or both of the other two of said three sets. One important embodiment of the novel prosthesis of the invention is a prosthesis adapted for use in repairing or replacing ligament or tendon tissue, in which embodiment the prosthesis has first and second opposed end portions adapted to be attached with the prosthesis in tension to the body of a patient, with said two end portions defining between them the longitudinal direction of the prosthesis, the fibers of the first set are oriented in substantially said longitudinal direction of the prosthesis the fibers of the first set have greater elasticity than the fibers of both of said second and third sets, and the fibers of the second and third sets have greater yield strength and Young's modulus than the fibers of the first set. By increasing (or decreasing) the braiding angle with other variables fixed, the resistance of this ligament or tendon prosthesis to deformation under longitudinal loading may be decreased (or increased). Preferably, the fibers of the second set in the ligament or tendon prosthesis are identical with the fibers of the third set. In a preferred design for a ligament or tendon prosthesis of the invention, the fabric element of said prosthesis has the shape of a cylindrical tube, the fibers of the first set are oriented in the longitudinal direction of said tube and the fibers of the second and third sets are helically-disposed in the wall of said tube.

The broad conception of the present invention comprises numerous other embodiments in addition to the ligament or tendon prosthesis discussed in the preceding paragraph, such as a vascular graft prosthesis in which the woven fabric element has the shape of a cylindrical tube, the fibers of the first set are oriented in the longitudinal direction of said tube, the fibers of the

second and third sets are helically-disposed in the wall of said tube, and the fibers of the first set have greater elasticity than the fibers of both of said second and third sets. The present invention also includes a prosthetic heart valve leaflet in the form of a sheet in which the fibers of the first set are oriented in the circumferential direction of the valve and have greater yield strength and Young's modulus than the fibers of the second and third sets, and the fibers of the second and third sets have greater elasticity than the fibers of the first set.

As used herein, the terms "yield strength" and "yield stress" are synonymous and refer to the tensile stress (in units of force per unit cross-sectional area) at which significant (i.e. greater than 0.2% of initial length) plastic deformation of a naturally-occurring or synthetic object occurs. The term "Young's modulus" refers to the ratio of the tensile stress placed on an object in elastic deformation to the resulting longitudinal strain. The term "elasticity" refers to the amount of recoverable elongation of a tensioned article, i.e. the percent elongation (expressed as a percentage of initial length) at the yield stress defined above. Note that as a matter of definition a "highly elastic" material (i.e. a material exhibiting a high elasticity) may be either highly resistant to elastic deformation (high Young's modulus) or not (low Young's modulus).

DETAILED DESCRIPTION OF THE INVENTION

The invention will be described in detail with reference to a preferred embodiment thereof, which is a ligament prosthesis. Reference to this embodiment does not limit the scope of the invention, which is limited only by the scope of the claims.

In the drawings:

FIG. **1** is a perspective view of a ligament or vascular prosthesis of the invention;

FIG. **2** is an enlarged view of the braided structure of the prosthesis of FIG. **1**;

FIG. **3** is a schematic representation of the load-strain behavior of the prosthesis of FIG. **1**, showing the effect of braiding angle;

FIGS. **4** and **5** depict the load-strain behavior of particular ligament prostheses of the invention, and

FIG. **6** is an exploded view of a heart valve prosthesis of the invention, in which only a portion of the braided structure of each valve leaflet is shown.

A ligament prosthesis **1** of the invention, which consists of a triaxially-braided fabric element **3** having opposed end portions **5** and **7** defining between them the longitudinal direction of the prosthesis, is shown in FIG. **1**. In the embodiment shown in FIG. **1**, prosthesis **1** and fabric element **3** are coincident, but (as will be explained below) this is not always necessarily so. Fabric element **3** in FIG. **1** has the form of a seamless cylindrical tube; although only a portion of the braided structure of fabric element **3** is shown in FIG. **1**, it is to be understood that said braided structure actually extends along the entire length of element **3** from end portion **5** to end portion **7**.

An enlarged view of the braided structure of fabric element **3** is shown in FIG. **2**, in which figure the vertical direction is the longitudinal direction of the prosthesis. Fabric element **3** contains interwoven first, second and third sets **9**, **11** and **13**, respectively, of fibers. The fibers of first set **9** are straight and oriented in substantially the same warp direction, i.e. the longitudinal direction of the prosthesis. The weft fibers of second and third sets **11** and **13** are helically-disposed in the wall of tubular fabric element **3** (see FIG. **1**) and are oriented at substantially the same acute braiding angle A (see FIG. **2**) with respect to the fibers of first set **9**. Each fiber of set **9** is held between the fibers of sets **11** and **13**. The weft fibers of sets **11** and **13** are preferably disposed in a two-up and two-down manner with respect to one another and in a one-up and one-down manner with respect to the fibers of set **9**. Other braiding patterns may alternatively be employed, such as the disposition of the fibers of sets **11** and **13** with respect to one another in a one-up and one-down or two-up and one-down manner. In FIG. **2**, braiding angle A is about 30°. Preferably, all of the fibers in fabric element **3** have circular cross-sections of about the same diameter. If desired, various fibers in one or both of the sets **11** and **13** may be dyed to provide a means to indicate the degree of tension and elongation being experienced by the prosthesis. For example, as illustrated in FIG. **1**, two fibers in each helical set may be dyed. As the prosthesis is tensioned, the spacing between the dyed fibers increases according to a predetermined relationship between tensile load and strain for the prosthesis. Thus, if implantation in a pretensioned state is desirable, the surgeon may be provided with a linear gauge showing the desired dyed fiber spacing at a desired state of pretension for the prosthesis.

Triaxially-braided fabrics such as the one depicted in FIG. **2** and the methods of manufacturing them in different configurations (flat sheets, tubes, patches, strips, etc.) are well known to those skilled in the art of manufacturing braided polymeric articles (see for example U.S. Pat. Nos. 4,191,218; 4,192,020 and 4,297,749). Braiding angles of from about 10° to about 80° are attainable. A significant advantage of using a triaxially-braided fabric element such as element **3** as a ligament prosthesis is that the element can be readily implanted in a tensioned state by attaching its two end portions, e.g. **5** and **7**, to the body of a patient (for example to the two bones making up a joint or to the two free ends of a severed natural ligament) by means of simple stapling or suturing techniques. Of course, if desired, a ligament or tendon prosthesis of the invention may include, in addition to a triaxially-braided fabric element, distinct means (for example those disclosed in U.S. Pat. No. 4,246,660) attached to the end portions of the fabric element for securing the prosthesis to the body of the patient.

In the ligament prosthesis **1** depicted in FIGS. **1** and **2** the longitudinally-oriented straight inlaid fibers of set **9** have greater elasticity than the fibers of helically-disposed sets **11** and **13**, while the fibers of sets **11** and **13** have greater yield strength and Young's modulus than the fibers of set **9**. As a result, the set **9** fibers provide the ligament prosthesis with the desired elasticity, while the set **11** and set **13** fibers provide the desired strength and resistance to longitudinal tensile deformation of the composite prosthetic article. The applied axial tensile load—% axial elongation curve for prosthesis **1** (not pretensioned) is shown schematically as curve C in FIG. **3**. Initially, the slope of the load vs. elongation curve is quite low as the load is borne primarily by the elastic fibers of set **9**. As elongation increases, however, the helically-disposed fibers of sets **11** and **13** become more aligned with the direction of elongation. As a result the slope of the load vs. elongation curve for the prosthesis increases sharply in the vicinity of point P_3.

Eventually the yield point of the prosthesis is reached, which is essentially equal to the yield point of the woven assembly of the fibers of sets **11** and **13**. An important characteristic of prosthesis **1** is the orientation of the elastic fibers of set **9** in the longitudinal direction of the prosthesis, which permits the storage of a large amount of elastic energy in the elongating fibers of this set. Significant additional elastic energy is stored in the compression of the fibers of set **9** by the fibers of sets **11** and **13** during elongation of the prosthesis. Only a small amount of applied work is dissipated as friction.

The fibers of the interwoven three sets in a prosthesis of the invention are preferably made of synthetic polymeric materials, although naturally-occurring (e.g. silk) and inorganic (e.g. stainless steel) fibers may also be used. If desired, biologically resorbable fibers may be employed. It is usually preferred that the fibers of the second and third sets be identical and equal in number. The elastic fibers of the first set in a ligament and/or tendon prosthesis of the invention such as prosthesis **1** may, for example, be selected from the group consisting of polyurethane polymers, silicone elastomers, polyester/polyether block copolymers, spandex-type polyurethane/polyether block copolymers, spandex-type polyurethane/polyester block copolymers, and hard elastic polypropylene. The strong and stiff fibers of the second and third sets in such a prosthesis may, for example, be selected from the group consisting of polyethyleneterephthalate, nylon, aromatic polyamide polymers such as Kevlar (E. I. du Pont de Nemours & Co.; Wilmington, Del.), isotactic polypropylene, polyglycolic acid and polylactic acid. Other suitable materials are readily apparent to those skilled in the art of polymer chemistry. As just one specific example, the fibers of first set **9** of prosthesis **1** may be made of a polyester/polyether block copolymer such as Hytrel (DuPont) and the fibers of sets **11** and **13** of polyethyleneterephthalate. Other alternative combinations of fibers are listed (non-exclusively) below:

Set 9	Set 11	Set 13
polyurethane polymer	nylon	nylon
polyurethane polymer	aromatic polyamide polymer	aromatic polyamide polymer
polyurethane polymer	isotactic polypropylene	isotactic polypropylene
polyurethane polymer	polyglycolic acid	polyglycolic acid
polyurethane polymer	polylactic acid	polylactic acid
polyurethane polymer	polyethyleneterephthalate	polyethyleneterephthalate
silicone elastomer	polyethyleneterephthalate	polyethyleneterephthalate
silicone elastomer	nylon	nylon
silicone elastomer	aromatic polyamide polymer	aromatic polyamide polymer
silicone elastomer	isotactic polypropylene	isotactic polypropylene
silicone elastomer	polyglycolic acid	polyglycolic acid
polyester/polyether block copolymer	polyethyleneterephthalate	nylon
polyester/polyether block copolymer	nylon	nylon
polyester/polyether block copolymer	aromatic polyamide polymer	aromatic polyamide polymer
spandex-type polyurethane/ polyether block copolymer	polyethyleneterephthalate	polyethyleneterephthalate
spandex-type polyurethane/ polyether block copolymer	nylon	nylon
spandex-type polyurethane/ polyether block copolymer	aromatic polyamide polymer	aromatic polyamide polymer
spandex-type polyurethane/ polyether block copolymer	polyglycolic acid	polyglycolic acid
spandex-type polyurethane/ polyether block copolymer	nylon	nylon
spandex-type polyurethane/ polyether block copolymer	aromatic polyamide polymer	aromatic polyamide polymer
spandex-type polyurethane/ polyether block copolymer	polyethyleneterephthalate	polyethyleneterephthalate
hard elastic polypropylene	polyethyleneterephthalate	polyethyleneterephthalate

Aside from the materials selected for the three sets of fibers in a prosthesis of the invention and the overall configuration and dimensions of the prosthesis, the resulting mechanical properties of the prosthesis, e.g. prosthesis **1** in FIGS. **1** and **2**, are also materially affected by the various braiding variables, e.g. the fiber diameters, braiding angle, braiding tension, density of windings, number ratio of fibers in the three sets and braiding pattern. Of considerable importance is the braiding angle, illustrated as angle A in FIG. **2**. As is shown schematically in FIG. **3**, the resistance of prosthesis **1** to deformation under axial loading in tension increases as the braiding angle is decreased (curve A to curve D). Furthermore, the percent elongation of prosthesis **1** (as a percentage of initial length) at which significant plastic deformation or breakage of the prosthesis commences decreases as the braiding angle is decreased. Thus it can be seen that, with all other variables fixed, the load-strain behavior of prosthesis **1** can be adjusted to approximate that of a natural ligament or tendon sought to be repaired or replaced by varying the braiding angle. Additionally, with all other variables fixed and the fibers of the second and third sets identical and equal in number, the load-strain behavior of prosthesis **1** can be substantially adjusted by varying the numerical ratio of fibers in the three sets, e.g. from 1 (longitudinal):1 (helical):1 (helical) to 0.5 (longitudinal):1 (helical):1 (helical), while maintaining a balanced prosthesis. The above-indicated change in number ratio would render the prosthesis more resistant to elongation under axial loading in tension.

In addition to mechanical properties, the wall porosity of a prosthesis of the invention may be varied in a predictable manner by altering the braiding variables, particularly the fiber diameters, braiding tension and density of windings. A relatively high porosity permits,

if desired, substantial tissue ingrowth into the wall of the fabric element of the prosthesis, while a relatively low porosity minimizes such ingrowth if it is not desired. Generally, tissue ingrowth is desired in a permanent prosthesis but not in a temporary one.

The triaxially-braided fabric element of a ligament and/or tendon prosthesis of the invention may have other shapes than the cylindrical tube shown in FIG. **1**. Thus, the fabric element may have the shape of a flattened cylindrical tube. As another example, the fabric element of a ligament and/or tendon prosthesis may have the shape of a flat elongated strip, in which the straight, longitudinally-oriented elastic fibers of the first set are disposed in essentially a single plane and each of the fibers of the second and third sets traverses said plane in a zig-zag manner (as depicted in FIG. **9** of U.S. Pat. No. 4,191,218) while maintaining a constant braiding angle.

The present invention is by no means limited to ligament and/or tendon prostheses, but includes prostheses for other soft tissue structures as well (e.g., blood vessels). Thus, for example, a vascular prosthesis of the invention such as an aortic graft prosthesis may have the same shape (but typically a different diameter) as the prosthesis **1** shown in FIG. **1**. In such a vascular prosthesis, the fibers of sets **9**, **11** and **13** are all elastic, with the straight fibers of longitudinally-oriented set **9** being more or less elastic, preferably more elastic, than the fibers of both of the other two sets. Accordingly, a tubular vascular prosthesis may be provided with high elasticity in the longitudinal direction as well as substantial elasticity in the radial direction to accomodate the pulsing flow of blood in vivo. If desired, such a tubular vascular prosthesis may include an impermeable elastic internal coating or tubular insert.

Additionally, a heart valve prosthesis of the invention (see FIG. **6**) may comprise a frame having a generally circular base defining the circumferential direction of the prosthesis and a plurality of spaced, generally parallel legs extending from the base; and a plurality of triaxially-braided fabric elements having the form of sheets and attached by conventional means to the frame in such a manner that they function as heart valve leaflets during the operation of the valve. Preferably, in each of said fabric elements, the fibers of the first set are oriented in the circumferential direction of the valve when the valve is in the open position, the fibers of the second and third sets traverse the first set of fibers in a zig-zag manner (as depicted in FIG. **9** of U.S. Pat. No. 4,191,218), the fibers of the first set have greater yield strength and Young's modulus than the fibers of the second and third sets, and the fibers of the second and third sets have greater elasticity than the fibers of the first set. Accordingly, an artificial heart valve prosthesis leaflet is provided that is capable of substantial elastic stretching in directions generally orthogonal to the circular base of the frame of the heart valve prosthesis.

The use of prostheses of the invention to repair or replace soft tissue requires only simple surgical procedures. After diseased or damaged soft tissue has been removed, the ends of a prosthesis of the invention may be readily attached to bone (e.g. with conventional bone staples) or to soft tissue (e.g. by suturing). Prostheses of the present invention may be cut to a desired length without unravelling. If desired, two tubular prostheses of the invention may be readily anastomosed in an end-to-end fashion. To prevent fraying of the triaxially-braided fabric element the free ends of the fibers at the edge of the element may be fused together, e.g. by ultrasonic welding or by dipping the edge of the element in a suitable coating material. A ligament and/or tendon prosthesis of the invention may be preconditioned before use by applying and releasing an axial tensile load (e.g. 60 lbs.) a number of times. In the case of an anterior cruciate ligament prosthesis, the prosthesis is preferably implanted in a longitudinally pretensioned state. Then, the observed load-strain behavior of the implanted prosthesis is that relative to an origin such as the origin O′ on curve C defined by the dotted abscissa and ordinate in FIG. **3**.

Conventional techniques (see for example the article by James, S. L., "Biomechanics of Knee Ligament Reconstruction", Clin. Orthoped. and Related Res., No. 146, pp. 90–101 (Jan.-Feb. 1980)) may be employed in attaching a ligament prosthesis of the invention to the patient's body. Preferably, a short end length of the prosthesis (e.g. prosthesis **1**) is folded over once (i.e. lap folded) and the attachment to the body effected at this doubled region. The surgical joining of a severed natural tendon may be facilitated by slipping a tubular prosthesis of the invention over the free end of one portion of the severed tendon, surgically joining the two portions of the tendon and then attaching the prosthesis to the two respective portions of the severed tendon. The prosthesis serves to support the healing tendon and can be removed after the healing has been accomplished.

By appropriate selection of braiding and other variables the mechanical properties of various natural human ligaments and tendons can be closely approximated by a prosthesis of the present invention. Often, in order to make such a match, it is desired that the prosthesis exhibit a tensile break point of at least about 75 kg. and, after initial pretension, an overall load modulus of from about 200 kg./(unit of strain based on pretensioned length) to about 600 kg./(unit of strain based on pretensioned length) over a range of substantially recoverable tensile elongation beginning at the pretensioned state and extending over a strain equal to at least about 25 percent of the initial pretensioned length of the prosthesis. Two examples of prosthesis **1** having these desired properties are set forth below. These examples are not to be construed as limiting the invention.

EXAMPLE 1

Set 9—Longitudinal fibers—48 ends—Hytrel Type 5556 polyester/polyether block copolymer monofilament (E. I. du Pont de Nemours & Co.; Wilmington, Del.)—220 denier

Set 11—Helical fibers—46 ends of 220 denier Dacron Type 52 polyethyleneterephthalate twisted multifilament (Du Pont) and 2 ends of 250 denier Dacron Type 55 polyethyleneterephthalate twisted multifilament (Du Pont) dyed with D & C green dye No. 6

Set 13—Helical fibers—same as set 11 Prosthesis configuration—flattened circular cylindrical tube 1.5 inches in length—21 mm. circumference

Braiding angle—45°

Braiding pattern of sets 11 and 13 with respect to one another—2-up and 2-down

Density of windings of sets 11 and 13 -35 picks per inch

Braiding tension—50 to 55 g. on longitudinal fibers, 3 oz. braider carrier springs on helical fibers

The above-described prosthesis exhibited the load-strain behavior shown in FIG. **4** (the origin is drawn with reference to the untensioned state). The prosthesis exhibits a tensile break point of 250 lbs. = 113 kg. If the

prosthesis is pretensioned to, for example, 10 lbs. tension (20% strain), it will exhibit an overall load modulus over a range of 37% of the pretensioned length of the prosthesis (equivalent to 44% of untensioned length) of (250-10) lbs./(0.37 unit of strain)=295 kg./(unit of strain). Above 20 lbs. load, the prosthesis will exhibit a substantially constant load modulus of (250-20)lbs./(0.31 unit of strain)=340 kg./(unit of strain). No distinct yield point is observed to breakage.

EXAMPLE 2

Set 9—Longitudinal fibers—48 ends—Lycra Type 127 spandex-type polyurethane/polyether block copolymer coalesced multifilament (du Pont) —280 denier
Sets 11 and 13—Helical fibers—same as in Example 1
Prosthesis configuration—same as in Example 1 except that circumference of tube is 19 mm.
Braiding angle—48°
Braiding pattern of sets 11 and 13 with respect to one another—2-up and 2-down
Density of windings of sets 11 and 13 -42 picks per inch
Braiding tension—20 to 25 g. on longitudinal fibers, 3 oz. braider carrier springs on helical fibers

The above-described prosthesis exhibited the load-strain behavior shown in FIG. 5 (the origin is drawn with reference to the untensioned state). The prosthesis exhibits a tensile break point of 202 lbs.=92 kg. If the prosthesis is pretensioned to, for example, 7 lbs. tension (40% strain), it will exhibit an overall load modulus over a range of 29% of the pretensioned length of the prosthesis (equivalent to 40% of untensioned length) of (202-7) lbs./(0.29 unit of strain)=305 kg./(unit of strain). Above 20 lbs. load the prosthesis will exhibit a substantially constant load modulus of (202-20) lbs./(0.23 unit of strain)=360 kg./(unit of strain). No distinct yield point is observed prior to breakage.

We claim:

1. A prosthesis for use in repairing or replacing ligament or tendon tissue, said prosthesis having first and second opposed end portions adapted to be attached with the prosthesis in tension to the body of a patient, with said two end portions defining between them the longitudinal direction of the prosthesis, and said prosthesis comprising a triaxially-braided fabric element containing interwoven first, second and third sets of fibers, with the fibers of said first set being elastic and oriented in substantially said longitudinal direction of the prosthesis, the fibers of said second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of said first set, the fibers of said first set having greater elasticity than the fibers of both of said second and third sets, the fibers of said second and third sets having greater yield strength and Young's modulus than the fibers of said first set, and said prosthesis exhibiting a tensile break point of at least about 75 kg.

2. A prosthesis of claim 1 wherein said braiding angle is from about 10° to about 80°, whereby the resistance of said prosthesis to longitudinal deformation under longitudinal tensile loading decreases as said braiding angle is increased.

3. A prosthesis of claim 2 wherein the fibers of said second set are identical with the fibers of said third set.

4. A prosthesis of claim 3 wherein the fibers of said first set are made of a polyester/polyether block copolymer and the fibers of said second and third sets are made of polyethyleneterephthalate.

5. A prosthesis of claim 3 wherein the fibers of said first set are made of a polyurethane/polyether block

copolymer and the fibers of said second and third sets are made of polyethyleneterephthalate.

6. A prosthesis of claim 3 wherein the fibers of said first set are made of a polyurethane/polyester block copolymer and the fibers of said second and third sets are made of polyethyleneterephthalate.

7. A prosthesis of claim 1 wherein said element has the shape of a cylindrical tube, the fibers of said first set are oriented in the longitudinal direction of said tube and the fibers of said second and third sets are helically-disposed in the wall of said tube.

8. A prosthesis of claim 1 wherein said element has the shape of a flat elongated strip, the fibers of said first set are oriented in the longitudinal direction of said strip in essentially a single plane and the fibers of said second and third sets traverse said plane in a zig-zag manner.

9. A prosthesis of claim 1 wherein said fabric element includes means to visually indicate the degree of extension of said prosthesis in tension.

10. A prosthesis of claim 3 wherein said triaxially-braided fabric element contains interwoven first, second and third sets of synthetic polymeric fibers, and said prosthesis exhibits, after initial pretension, an overall load modulus of from about 200 kg./unit of strain) to about 600 kg./(unit of strain) over a range of substantially recoverable tensile elongation amounting to at least about 25 percent of the initial pretensioned length of the prosthesis.

11. A vascular prosthesis comprising a triaxially-braided fabric element containing interwoven first, second and third sets of fibers, with said element having the shape of a cylindrical tube, the fibers of said first set being elastic and oriented in the longitudinal direction of said tube, the fibers of said second and third sets being elastic and helically-disposed in the wall of said tube at substantially the same acute braiding angle with respect to the fibers of said first set, and the fibers of said first set having greater elasticity than the fibers of both of said second and third sets.

12. A prosthesis of claim 11 wherein said braiding angle is from about 10° to about 80°.

13. A heart valve prosthesis comprising:

- a frame having a generally circular base defining the circumferential direction of the prosthesis and a plurality of spaced, generally parallel legs extending from said base; and
- a plurality of triaxially-braided fabric elements having the form of sheets and attached to said frame in such a manner that they function as heart valve leaflets during the operation of the valve, with each of said fabric elements containing interwoven first, second and third sets of fibers, with the fibers of said first set being oriented in substantially the same direction and the fibers of said second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of said first set, and wherein, in each of said fabric elements, the fibers of said first set are oriented in the circumferential direction of said valve when said valve is in the open position, the fibers of said second and third sets traverse said first set of fibers in a zig-zag manner, the fibers of said first set have greater yield strength and Young's modulus than the fibers of both of said second and third sets, and the fibers of said second and third sets have greater elasticity than the fibers of said first set.

14. A prosthesis of claim 13 wherein said braiding angle is from about 10° to about 80°.

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